UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P., and
RHODES TECHNOLOGIES,

Plaintiffs,

v.

VARAM, INC. and KVK-TECH, INC.

Defendants.

Civ. Action No. 10-cv-6038 (SHS)
Civ. Action No. 11-cv-0766 (SHS)
Civ. Action No. 12-cv-2814 (SHS)
Civ. Action No. 12-cv-6047 (SHS)

Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF VARAM, INC.'S SUMMARY JUDGMENT MOTION OF INVALIDITY OF THE THREE CHAPMAN PATENTS FOR INDEFINITENESS, OR, IN THE ALTERNATIVE, ANTICIPATION AND OBVIOUSNESS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

INTRODUCTION

Defendant Varam, Inc. ("Varam") makes this motion for summary judgment of the invalidity of the asserted claims in this action from the Three Chapman Patents (*i.e.*, U.S. Patent Nos. 7,674,799 (the "'799 patent"), 7,674,800 (the "'800 patent"), and 7,683,072 (the "'072 patent"), three of the four patents-in-suit), for their indefiniteness under 35 U.S.C. § 112. A patent claim is invalid if it is indefinite. The current Federal Circuit pronouncement of this law is that a claim is indefinite if it is "not amenable to construction or [is] 'insolubly ambiguous.'" *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005).

The asserted claims of the '799 and '072 patents contain two irreconcilable and insoluble elements, which render the claims nonsensical and invalid due to indefiniteness. A "first" element is directed to a specific impurity, "14-HC" (*i.e.*, 14-hydroxycodeinone), that can be completely absent, while a "second" element requires the presence of 14-HC. It is impossible to have something absent and present at the same time. The claims do not make sense.

Specifically, each asserted claim of the '799 and '072 patents has the first element that includes having absolutely no 14-HC (*i.e.*, having less than 25 ppm includes having zero):

> An oral dosage form comprising: (1) from about 5 mg to about 320 mg oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone . . . ('799, claim 1)
>
> or
>
> An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone . . . ('072, claim 1)

But each asserted claim also has the second element that requires that a portion of 14-HC be derived from 8α:

> wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone . . . ('799, claim 1 and '072, claim 1)

It is impossible to have 14-HC be both absent and present at the same time. This language cannot be reconciled without re-writing the claim, a process courts are not permitted to do, thus rendering the claims invalid.

Alternatively, if the Court finds a basis to rewrite the claims so that the second element is not necessary, *i.e.*, zero 14-HC is included via the first element so there does not need to be a portion derived from "8α" (*i.e.*, 8α,14-dihydroxy-7,8-dihydrocodeinone) to meet the second element, or some similar rationale, then the claims are anticipated and obvious by the prior disclosure of pure oxycodone hydrochloride used in oral dosage forms.

The asserted claims of the '800 patent suffer from similar defects. One of the two independent claims, claim 1, requires that the "oxycodone salt" be "substantially free" of 14-HC. "Substantially free" is clearly at most a very low amount in any vernacular, although it is never mentioned in the specification. However, claim 1's dependent claims (claims 19-21 and 32-34) require that the "oxycodone salt" must instead have "less than about 25 [or 15 or 10] ppm" 14-HC. The salt cannot meet these very different requirements at the same time. This problem is further confounded because the other independent claim, claim 57, is also insoluble. It requires the "oxycodone salt" to be "substantially free" of 14-HC and the same "oxycodone salt" to "have less than 25 ppm" 14-HC all within the same claim. Claims 73, 74, 78 and 79 require the same claim 57 oxycodone salt to have "less than 25 ppm" (for the second time, as it was already in the independent claim), "less than 15 ppm," and "less than 10 ppm," of the impurity 14-HC.

FACTS

There are no genuine issues of material fact concerning the underlying basis for this motion. The facts are as follows:

1. Three of the four patents-in-suit are the Three Chapman Patents, each of which shares a specification that is the same for all purposes of this motion. Exhibit 1 (collection of the '799, '072 and '800 patents).

I. The Insoluble Elements Of The '799 And '072 Asserted Claims

1. Purdue is asserting that Varam infringes the following "asserted claims" of the '799 and '072 patents: claims 3 and 19 of the '799 Patent and claims 1, 4, and 5 of the '072 Patent.

2. Each of the asserted claims contains a first element directed to having oxycodone hydrochloride with *less than* a certain amount of 14-HC, either explicitly or because it is a dependent claim that references a claim with the element. Exhibit 2 (chart highlighting these elements in red in the asserted claims).

3. The term "*less than*" includes zero.

4. Example 6 of the '799 and '072 patents reported that an oxycodone hydrochloride preparation the inventors made contained no detectable 14-HC (*i.e.*, less than 5 ppm). Specifically, it states that "The results for Example 2 utilizing the procedure of Example 6 gave a result of <5 ppm of codeinone and <5 ppm of 14-hydroxycodeinone." *E.g.*, '799 col. 34, lines 43-45.

5. Each of the asserted claims also contains a second element that requires "at least a portion of the" 14-HC to be "derived from" 8α. Exhibit 2 (chart highlighting these elements in yellow in the asserted claims).

6. It is impossible to have the zero 14-HC that is included in the first element and still have "a portion" of 14-HC for the second element, rendering the claims indefinite.

7. Alternatively, if the Court finds that it is possible to read the claims to have zero 14-HC for the first element and have the second element not apply, or some similar alternative

construction of the claims, then a "pure oxycodone hydrochloride" disclosed in the prior art would meet the first element and need not meet the second element.

8. The prior art included pure oxycodone hydrochloride. For example, Chiu et al. U.S. Patent No. 6,177,567 (the "Chiu '567 patent"; Exhibit 3) describes making an oxycodone without any 14-HC. During the prosecution of the '800 patent, Purdue admitted that any oxycodone hydrochloride made from the Chiu '567 patent's oxycodone would lack 14-HC:

> "one skilled in the art would have expected that the oxycodone hydrochloride salt prepared from the oxycodone free base according to the Chiu patent would not have any detectable 14-hydroxycodeinone." Exhibit 4 ('800 patent prosecution, Response dated April 22, 2008, p. 11).

9. The Chiu '567 patent anticipates the asserted claims of the '072 under at least 35 U.S.C. § 102(a)(b) and (e). It was issued on January 23, 2001, more than a year before the earliest possible filing of the '799 and '072 related applications, the earliest of which was filed on March 30, 2004.

10. It was in the knowledge of a person of ordinary skill in the art to convert oxycodone base to the oxycodone hydrochloride that was commercially sold. *E.g.*, Exhibit 1 ('799 patent reporting on prior art at col. 2, lines 2-12); *see also* the Lin '370 patent addressed below. The Chiu '567 patent in combination with either the knowledge of a person skilled in the art, who would know how to make sustained release dosage forms, or U.S. Patent No. 5,656,295 ("the Oshlack '295 patent") (Exhibit 5; filed on November 27, 1991), the latter of which discloses including oxycodone hydrochloride in an oral dosage form with a pharmaceutically acceptable excipient (*e.g.*, Exhibit 4, col. 13, lines 48-62), renders the asserted claims of the '799 patent anticipated and/or obvious under 35 U.S.C. §§ 102 and 103.

11. .The prior art also includes Lin et al. U.S. Patent No. 6,864,370 (the "Lin '370 patent"; Exhibit 6), which describes the preparation of oxycodone hydrochloride from

oxydocone base that results in "pure oxycodone hydrochloride," without evidence of any 14-HC. Exhibit 3, Example 7, col. 7, lines 28-40.[1]

12. Lin used the same concentrated hydrogen chloride to salt the oxycodone base as recommended by the '799 and '072 patents. *E.g.*, Exhibit 6, Example 7, col. 7, line 35; Exhibit 1, col. 8, lines 4-23. Specifically, the '799 patent states that "During salt formation reactions known in the art, the 8,14-dihydroxy-7,8-dihydrocodeinone component is converted to 14-hydroxycodeinone by acid-catalyzed dehydration. … In such an embodiment, the amount of hydrochloric acid is an amount of greater than 1 molar equivalent as compared to the oxycodone free base." *Id*. In Lin, the amount of hydrochloric acid is an amount of greater than 1 molar equivalent as compared to the oxycodone free base.[2]

13. The Lin '370 patent anticipates the asserted claims of the '072 under at least 35 U.S.C. § 102(a) and (e). It was filed on June 5, 2003, well before the earliest possible filing of the '799 and '072 related applications, the earliest of which was filed on March 30, 2004.

14. The Lin '370 patent in combination with either the knowledge of a person skilled in the art, who would know how to make sustained release dosage forms, or the Oshlack '295 patent (Exhibit 5; filed on November 27, 1991), the latter of which discloses including oxycodone hydrochloride in an oral dosage form with a pharmaceutically acceptable excipient

[1] Lin's preparation of oxycodone hydrochloride states: "8.1 g of oxycodone obtained in Example 6 and 80 ml of ethanol are placed in a 250 ml round-bottomed flask. The mixture is heated to reflux. Into the hot mixture is added 10 ml of a concentrated solution of hydrogen chloride in isopropanol. The mixture is cooled and stirred at 0-5°C for 1-2 hours. The product is filtered off and the filter cake is washed with a small amount of cold ethanol. After drying in vacuo (*e.g.*, 50 mm Hg) at 30-40°C., 77 g (85% yield) of pure oxycodone hydrochloride is obtained."

[2] Purdue cannot dispute that a concentrated solution of hydrogen chloride is a standard and thus the amount Lin uses is a 4.5 higher molar equivalent concentration, thus anticipating the teaching of the Three Chapman Patents.

(*e.g.*, Exhibit 4, col. 13, lines 48-62), renders the asserted claims of the '799 patent anticipated and/or obvious under 35 U.S.C. §§ 102 and 103.[3]

15. No secondary considerations of non-obviousness could possibly apply to a claim construed in the manner described as this alternative, where the subject matter is directed to merely a pure oxycodone hydrochloride that is in the prior art. *See also* Exhibit 7, pp. 40, 42 (finding of interference Board that no secondary considerations applied to either party's claims: "there is no credible evidence before us which would make out a case that any unexpected result is achieved by use of the particular parameters ultimately described to be useful by Casner" and "Here, on the other hand, the FDA and the pharmaceutical industry were faced with a problem which seems to have been solved in rather short order by those skilled in the art using their sophisticated skilled through application of known techniques reported in the literature or which were otherwise known.").

II. The Insoluble Elements Of The '800 Patent Asserted Claims

16. Purdue is asserting that Varam infringes the following "asserted claims" of the '800 patent: claims 1, 19-21, 23-24, 26, 30-34, 57, 67-68, 70, 73-74 and 76-79.

17. Each of the asserted claims contains a requirement that the oxycodone salt be "substantially free" of 14-HC, either explicitly (*i.e.*, claims 1 and 57) or because it is a dependent claim that references a claim with the element. Exhibit 2 (chart highlighting these elements in red in the asserted claims).

[3] As separate and alternative grounds of invalidity, because these claims are product-by-process claims, and the product was invalid over the prior art cited in Purdue's previous interference for the reasons cited by the Board and Federal Circuit, as addressed in Varam's summary judgment of invalidity based on obviousness and collateral estoppel, filed concurrently herewith. Exhibits 7 and 8 (Board and Federal Circuit opinions, respectively).

18. The term "substantially free" does not appear in the specification of the Three Chapman Patents. Exhibit 1. In the context of a pharmaceutical patent that is directed to the removal and total elimination of an impurity (*e.g.*, '800 Example 6, col. 34, lines 13-14, " <5 ppm" 14-HC is below the level of detectability for the inventors so none was detected), the term would mean that there is zero to a very low amount of the impurity.

19. Despite the incorporation of "substantially free" into every asserted claim of the '800 patent, the patent also has dependent claims (*i.e.*, claims 19-21, 32-34, 73-74, 77-78) directed to having "less than 25 ppm", "less than 15 ppm" and "less than 10 ppm" of the impurity. Claim 57 even has the "substantially free" and "less than 25 ppm" in the same claim. "Substantially free" thus has no discernible meaning. Therefore, all of the asserted claims of the '800 patent are insoluble and invalid.

LEGAL STANDARDS

"[T]he patent laws require inventors to describe their work in 'full, clear, concise, and exact terms,' 35 U.S.C. § 112, [¶ 2,] as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730-31 (2002). This has come to be known as the "definiteness" requirement under 35 U.S.C. § 112, ¶ 2. *See Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). "Because the claims perform the fundamental function of delineating the scope of the invention . . . the purpose of the definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude. . ." *Datamize,* 417 F.3d at 1347 (internal citations omitted). "Claim

terms must provide a discernible boundary between what is claimed and what is not claimed. . ." *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1367 (Fed. Cir. 2011).

Determining whether a claim is adequately "definite" is a question of law. *See Personalized Media Commc'ns, LLC v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998) ("A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims."). The standard for proof of indefiniteness is met "where an accused infringer shows by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Halliburton*, 514 F.3d at 1249-50. When a claim is "not amenable to construction or [is] insolubly ambiguous," it is indefinite. *Datamize*, 417 F.3d at 1347. Claims are invalid as indefinite when the claim elements are internally inconsistent. *See*, *e.g.*, *Competitive Techs., Inc. v. Fujitsu Ltd.*, 185 F. App'x 958, 965-66 (Fed. Cir. 2006).

Further, when a claim is found to be indefinite, a court cannot rewrite the claim to preserve its validity either. *See Chef America Inc. v. Lamb Weston, Inc.*, 358 F.3d 1371, 1375 (Fed. Cir. 2004); *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1349 (Fed. Cir. 2002) ("It is not our function to rewrite claims to preserve their validity."). Moreover, "it is of no moment that the contradiction is obvious: semantic indefiniteness of claims 'is not rendered unobjectionable merely because it *could* have been corrected.'" *Id.* (quoting *In re Hammack*, 427 F.2d 1384, 1388 n.5 (C.C.P.A. 1970)) (emphasis original).

In addition, the validity of claims necessarily requires, among other things, novelty in view of the prior art. Lack of novelty, *i.e.*, anticipation under 35 U.S.C. § 102, requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *See*

Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 20 (Fed. Cir. 2000). Thus, a prior art reference anticipates a claim if the reference discloses the claimed invention such that persons of ordinary skill in the art could have taken its teachings in combination with their own knowledge of the particular art and be in possession of the invention. *See In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995). Even if the prior art reference does not expressly disclose each limitation, it may still invalidate the claim under the doctrine of inherency where the prior art includes the claim limitation as an innate property or functional characteristic. *See Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention; the doctrine of inherency only requires that the subject matter is in fact inherent in the prior art reference. *Id.*

Even if each and every element of a claim is not shown in a single prior art reference, a claim may nonetheless be invalid under 35 U.S.C. § 103(a) if subject matter within its scope would have been obvious to a person of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

United States prior art patents, such as the prior art Lin and '295 patents, are presumed to be correct and enabled in their teaching. *See*, *e.g.*, *In re Weber*, 405 F.2d 1403, 1407 (C.C.P.A. 1969) (there is a "strong presumption that the process of a patent if used by one skilled in the art will produce the results alleged by the patentee"); *In re Bowen*, 492 F.2d 859, 863 (C.C.P.A. 1974) (a patent specification's disclosure is presumptively accurate); *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971) (same); *In re Antor Media Corp.*, 689 F.3d 1282, 1287 (Fed. Cir. 2012) ("both claimed and unclaimed materials disclosed in a patent are presumptively enabling") (citing *Amgen, Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1355 (Fed. Cir. 2003)).

ARGUMENT

The asserted claims of the '799, '072 and '800 patents do not make sense. It is not possible to lack 14-HC but also have 14-HC derived from 8α. And there is no discernible definition for a salt that is "substantially free" of 14 H-C. This is not a hypothetical concern – an object of the patent, and a clear and obvious benefit, was to eliminate or reduce this impurity as much as possible to zero. 14-HC has been alleged to cause untoward effects to DNA. Indeed, Example 6 reported that the inventors had reduced 14-HC to a level below their ability to detect it (*i.e.*, less than 5 ppm).

Concerning the '799 and '072 patents, the Example 6 result had no detectable 14-HC and thus it could not also have 14-HC derived from 8α. These two claim elements, in which the claimed composition can have no 14-HC and at least a portion of the non-existent 14-HC must be derived from 8α, are contradictory to each other, making the asserted claims of the '799 and '072 patents internally inconsistent and nonsensical. A person ordinary of skill in the art cannot possibly discern the boundary delineating the scope of the invention recited in these asserted claims. These claims, therefore, are invalid due to indefiniteness. *See*, *e.g.*, *Competitive Techs.*, 185 F. App'x at 965-66 (claims with internally inconsistent elements invalid due to indefiniteness); *Intermec Techs. Corp. v. Palm Inc.*, 738 F. Supp. 2d 522, 547 (D. Del. 2010) (claim "necessarily invalid due to the irreconcilable contradiction within the patent"); *Realtime Data, LLC v. Packeteer, Inc.*, 652 F. Supp. 2d 791, 799 (E.D. Tex. 2009) (claim element "inconsistent with the remainder of the claims, specification, and prosecution history" rendered the claim nonsensical and invalid as being indefinite).

Concerning the '800 patent asserted claims, the drafter mistakenly added several new and/or inconsistent impurity levels to the independent and dependent claims that cannot be reconciled with one another, leaving the claims nonsensical. *Id*.

It may be suggested that the claims could have been drafted to make sense. They could have said "greater than 5 ppm but less than 25 ppm" or they could have said "wherein at least a portion of any present 14-HC is derived from 8α." The "substantially free" limitation could have been removed. However, these language changes were not made in the claims and courts are not permitted to rewrite the claims to add language even though it would then have them make sense. *See Chef America*, 358 F.3d at 1375; *Allen Eng'g*, 299 F.3d at 1349.

Alternatively, if the Court construes the '799 and '072 claims to read-out the element that there must be 14-HC that is derived from 8α when no 14-HC is present, then the claims are invalid over the prior disclosure of pure oxycodone hydrochloride and its use in oral dosage forms in the Chiu '567 and Lin '370 patents, alone or in combination with the Oshlack '295 patent, and, alternatively, for the reasons applied in Purdue's previous interference. *See In re Graves*, 69 F.3d at 1152; *KSR*, 550 U.S. at 415. There is no evidence that the Chiu or the Lin oxycodone hydrochloride was not pure, a finding further compelled by the presumption that prior art United States patents are presumed to be correct and enabled (*Weber*, 405 F.2d at 1407; *Antor*, 689 F.3d at 1287) and because Purdue admitted that the Chiu product would be pure while Lin states its product is pure and it used the same excess of acid as is taught by the Three Chapman Patents.

CONCLUSION

For the foregoing reasons, Varam respectfully requests that the Court grant summary judgment that the asserted claims of the '799, '072 and '800 patents are invalid due to indefiniteness, or, alternatively, anticipation and obviousness.

Dated: October 18, 2012

Respectfully submitted,

By: */s/ Donald L. Rhoads*

Donald L. Rhoads, Esq.
Mary W. Richardson, Esq.
Geoffrey G. Hu, Esq.
Michèle Steiner, Esq.
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
1177 Avenue of the Americas
New York, New York 10036
(212) 715-9100

Attorneys for Defendant Varam, Inc.

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of the preceding document has been caused to be served via ECF on at least the following counsel of record for Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies this 18th day of October, 2012:

Pablo Daniel Hendler
Sona De
Ropes & Gray, LLP (NYC)
1211 Avenue of the Americas
New York, NY 10036
(212) 596-9000
Fax: (212)-596-9090
Email: pablo.hendler@ropesgray.com

Robert J. Goldman
Ropes & Gray, LLP (CA)
1900 University Avenue
6th Floor
East Palo Alto, CA 94303
(650)-617-4035
Fax: (650)-617-4090
Email: robert.goldman@ropesgray.com

Dated: October 18, 2012
New York, New York

/s/ Geoffrey G. Hu
Geoffrey G. Hu, Esq.